

Message Text

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70

ORIGIN HEW-04

INFO OCT-01 EUR-12 NEA-10 ISO-00 SCI-04 MED-03 RSC-01 /035 R

66616

DRAFTED BY DHEW/FDA/JRWEINROTH, M.D.

APPROVED BY SCI/SA:MSBEAUBIEN

DHEW/OIH/MACODDING

EUR/NSC-IG:JROUSE

NEA/IAI:EWBIZIC

SCI/SA:AERICHMOND (INFO)

----- 109716

R 112123Z OCT 74

FM SECSTATE WASHDC

TO AMEMBASSY BRUSSELS

AMEMBASSY COPENHAGEN

AMEMBASSY PARIS

AMEMBASSY BONN

AMEMBASSY ROME

AMEMBASSY STOCKHOLM

AMEMBASSY TEL AVIV BY POUCH

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E.O. 11652: N/A

TAGS: ETRD, EIND, TBIO, BE, DA, FR, GW, IS, IT, SW

SUBJECT: RECALL OF MEDICAL DEVICE

1. FDA ADVISES THAT FENWALL LABORATORIES, DIVISION OF TRAVENOL LABS, MORTON GROVE, ILLINOIS, 60053 IS "RECALLING" ALL LOTS OF THEIR FENWALL DOUBLE ELUTRA-PAK UNIT CODE 4R 2400, TO THE USER LEVEL.

2. A TRANSFUSION REACTION IN A PATIENT AT THE MOBILE INFIRMARY, MOBILE, ALABAMA, ON 8/13/74 DISCLOSED POSSIBLE CONTAMINATION MAY HAVE OCCURRED AS A RESULT OF A LEAK IN THE SEAL OF THE INJECTOR AND THE SEAL BODY. THERE HAVE BEEN 25 COMPLAINTS OF LEAKING SEALS SINCE 3/30/74.

3. WHILE THE FIRM IS NOT, REPEAT, NOT REMOVING THE UNITS FROM
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THE MARKET, THEY ARE INSTRUCTING CUSTOMERS NOT REPEAT NOT

TO PROCESS BLOOD THROUGH THE UPPER (BLUE) HALF OF THE INJECTOR
AND SEAL BODY BUT RATHER TO PROCESS BLOOD THROUGH THE LOWER
(WHITE) HALF ONLY.

4. FOREIGN CONSIGNEES, AS FOLLOWS:

HOSPITAL BARRIERE
LIEGE, BELGIUM

RIGHOSPITALET BLODBANKEN
BLEGDAMULIN 9
2100 COPENHAGEN, DENMARK

CNTS
6 RUE ALEXANDRE COBANEL
75 739 PARIS, FRANCE

DOK AACHEN
GOELHESTRASSE 27-29
251 AACHEN, GERMANY

DOK BLUTSPHESSEN
SAUBHOFSTRASSE 1
6 FRANKFURT 71, GERMANY

DOK HAGEN
BUSCHEYSTRASSE 15A
58 HAGEN, GERMANY

DR. MALCHI
BEILINSON HOSPITAL
PETACH TIKVA, ISRAEL

OSPEDALE GALLIERA
GENOVA, ITALY

OSPEDALE DI SUMMA
BRINDISI, ITALY

AKADEMISKA SJUKHUSET
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BLODCENTRALEN
S-75014 UPPSALA, SWEDEN

5. POST ARE REQUESTED TO INFORM CONSIGNEES OF DETAILS OF
"RECALL" AND FIRMS RECOMMENDATIONS REGARDING USE OF THIS
DEVICE.
INGERSOLL

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 11 OCT 1974
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1974STATE225156
Document Source: CORE
Document Unique ID: 00
Drafter: FDA/JRWEINROTH, M.D.
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D740291-0944
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1974/newtext/t19741051/aaaabrly.tel
Line Count: 114
Locator: TEXT ON-LINE, ON MICROFILM
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Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
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Previous Channel Indicators:
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
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Review Authority: golinofr
Review Comment: n/a
Review Content Flags:
Review Date: 11 MAR 2002
Review Event:
Review Exemptions: n/a
Review History: RELEASED <11 MAR 2002 by chappeld>; APPROVED <30 JUL 2002 by golinofr>
Review Markings:

Declassified/Released
US Department of State
EO Systematic Review
30 JUN 2005

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: RECALL OF MEDICAL DEVICE
TAGS: ETRD, EIND, TBIO, BE, DA, FR, GE, IS, IT, SW, US
To: BRUSSELS MULTIPLE
Type: TE
Markings: Declassified/Released US Department of State EO Systematic Review 30 JUN 2005